UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

TATIANA KOROLSHTEYN, on behalf of herself and all others similarly situated, Plaintiff, v. COSTCO WHOLESALE CORPORATION and NBTY, INC., Defendants.	Case No.: 3:15-cv-709-CAB-RBB **ORDER** **(1) GRANTING MOTION FOR SUMMARY JUDGMENT** **(2) DENYING MOTION TO DECERTIFY THE CLASS AND DAUBERT MOTIONS AS MOOT** [Doc. Nos. 237, 238, 241, 242, 243]

This matter comes before the Court on Defendants' motion to decertify the class and motion for summary judgment. [Doc. No. 238.] The Court finds them suitable for determination on the papers submitted and without oral argument. *See* S.D. Cal. CivLR 7.1(d)(1). For the reasons set forth below, Defendants' motion for summary judgment [Doc. No. 238] is granted. Defendants' motion to decertify the class and both parties' *Daubert* motions are denied as moot.

I. BACKGROUND

This case arises out of alleged false statements on the labels of TruNature Gingko

Biloba with Vinpocetine ("TruNature Gingko"), which is manufactured by Defendant NBTY, Inc. ("NBTY") and sold at the stores of Defendant Costco Wholesale Corporation ("Costco"). The labels of TruNature Gingko represent that the product "supports alertness & memory," that "Gingko biloba can help with mental clarity and memory," and that "[i]t also helps maintain healthy blood flow to the brain to assist mental clarity and memory, especially occasional mild memory problems associated with aging" (collectively, the "Label Claims"). [Doc. No. 100 at ¶ 1.[1]] According to the third amended complaint (the "TAC"), these representations are false because studies show that Gingko biloba and vinpocetine do not provide any mental clarity, memory or mental alertness benefits. [*Id.* at ¶ 2.]

Lead Plaintiff Tatiana Korolshteyn alleges she bought a bottle of TruNature Gingko based on the allegedly false representations on the product label and filed this lawsuit on behalf of herself and a class of consumers who purchased TruNature Gingko in California. The TAC asserts two claims: (1) violation of California's unfair competition law (the "UCL"), California Business & Professions Code § 17200 *et seq.*; and (2) violation of California's Consumer Legal Remedies Act ("CLRA"), California Civil Code § 1750 *et seq*. The prayer for relief asks for restitution and disgorgement of Defendants' revenues, actual, statutory and punitive damages, and attorneys' fees and costs. [*Id.* at 15.]

On March 16, 2017, the Court granted Plaintiff's motion to certify a class consisting of "all California consumers who, within the applicable statute of limitations, purchased TruNature Gingko Biloba with Vinpocetine until the date notice is disseminated." [Doc. No. 158 at 14.] On August 23, 2017, the Court granted Defendants' motion for summary judgment [Doc. No. 220], and Plaintiff timely appealed. On March 29, 2019, the Ninth Circuit remanded this case for further proceedings, reversing the grant of summary judgment and affirming the denial of the *Daubert* motions. [Doc. No. 235.] Defendants

[1] Document numbers and page references are to those assigned by CM/ECF for the docket entry.

now move to decertify the class and renew their motion for summary judgment. [Doc. No. 238.] Also pending before the Court are renewed motions by both parties to exclude evidence and testimony from their respective experts. Among other arguments, Defendants contend in their renewed motion for summary judgment that Plaintiff's state false advertising claims are preempted under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., as amended by the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343 *et seq*. [Doc. No. 238-1 at 25–27.] The Court is persuaded and grants Defendants' motion for summary judgment on preemption grounds. The motion to decertify the class and *Daubert* motions are therefore moot.

II. LEGAL STANDARD

A. Summary Judgment

A party is entitled to summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). To avoid summary judgment, disputes must be both 1) material, meaning concerning facts that are relevant and necessary and that might affect the outcome of the action under governing law, and 2) genuine, meaning the evidence must be such that a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Cline v. Indus. Maint. Eng'g & Contracting Co.*, 200 F.3d 1223, 1229 (9th Cir. 2000).

The initial burden of establishing the absence of a genuine issue of material fact falls on the moving party. *See Celotex Corp.*, 477 U.S. at 323. If the moving party can demonstrate that its opponent has not made a sufficient showing on an essential element of his case, the burden shifts to the opposing party to set forth facts showing that a genuine issue of disputed fact remains. *Id.* at 324. When ruling on a summary judgment motion, the court must view all inferences drawn from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). However, "[t]he district court need not examine the entire file for

evidence establishing a genuine issue of fact, where the evidence is not set forth in the opposing papers with adequate references so that it could conveniently be found." *Carmen v. San Francisco Unified Sch. Dist.*, 237 F.3d 1026, 1031 (9th Cir. 2001).

B. Express Preemption under the NLEA

Federal preemption can be either express or implied. *See Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152–53 (1982). Express preemption exists when a statute explicitly addresses preemption. *See Chicanos Por La Causa, Inc. v. Napolitano*, 558 F.3d 856, 863 (9th Cir. 2009). The NLEA expressly preempts any state law that establishes "any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title." 21 U.S.C. § 343-1(a)(5). The NLEA classifies dietary supplements as food; indeed, § 343-1 ("National uniform nutrition labeling") and § 343 ("Misbranded food") fall under the NLEA's "Food" subchapter. "Thus, a structure/function claim also constitutes a claim 'made in the label or labeling of food.'" *Dachauer v. NBTY, Inc.*, 913 F.3d. 844, 847 (9th Cir. 2019) (citing § 343-1(a)(5)). The NLEA provides that no state may "directly or indirectly establish . . . any requirement for the labeling of food that is not identical" to the federal requirements. 21 U.S.C. § 343-1(a)(5). The phrase "not identical to" means "that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food [that] . . . [a]re not imposed by or contained in the applicable [federal regulation] . . . or [d]iffer from those specifically imposed by or contained in the applicable [federal regulation]." 21 C.F.R. § 100.1(c)(4).

C. Structure/Function Claims under the NLEA

The NLEA distinguishes between "*structure/function claims*" and "*disease claims*" that manufacturers make about their products. A structure/function claim "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function," but "may not claim to diagnose,

mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6). A disease claim, conversely, "claims to diagnose, mitigate, treat, cure, or prevent disease," either explicitly or implicitly (such as by claiming that a product treats a disease's "characteristic signs or symptoms"). 21 C.F.R. § 101.93(g)(2)(ii). Structure/function claims must meet three requirements: (1) the manufacturer has substantiation that the statement is truthful and not misleading; (2) the statement contains a prominent disclaimer that the Food and Drug Administration ("FDA") has not evaluated the statement and that the product "is not intended to diagnose, treat, cure, or prevent any disease"; and (3) the statement itself does not "claim to diagnose, mitigate, treat, cure, or prevent" disease. 21 U.S.C. § 343(r)(6).

Although the FDCA requires manufacturers to have substantiation for their structure/function claims, California law does not allow private plaintiffs to demand substantiation for advertising claims. *Dachauer*, 913 F.3d. at 847 (9th Cir. 2019) (citing *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal.App.4th 1336, 1344 (2003)). The FDCA does not define the term "substantiation," but FDA guidance advances a common sense interpretation of "substantiation," as meaning "competent and reliable scientific evidence." *See Kaufman v. CVS Caremark Corp.*, 836 F.3d 88, 93 (1st Cir. 2016). The FDA has published guidance in the Federal Register discussing, among other things, acceptable structure/function claims. *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body*, 65 Fed. Reg. 1000–01 (Jan. 6, 2000). "The guidance recognizes that structure/function claims may use general terms such as 'strengthen,' 'improve,' and 'protect,' as long as the claims 'do not suggest disease prevention or treatment.'" *Dachauer*, 913 F.3d. at 847 (citing 65 Fed. Reg. at 1028.)

III. ANALYSIS

Here, the NLEA preempts Plaintiff's state false advertising claims. Defendants' Label Claims are permissible structure/function claims pursuant to the FDA's guidance and meet all the federal labeling requirements. Defendants' Label Claims do not suggest

disease prevention or treatment and use acceptable general terms to represent that the product "supports alertness & memory," that "Gingko biloba can help with mental clarity and memory," and that "[i]t also helps maintain healthy blood flow to the brain to assist mental clarity and memory, especially occasional mild memory problems associated with aging." [Doc. No. 100 at ¶ 1.]

Plaintiff's opposition to Defendants' preemption argument is sparse. Plaintiff contends that her claims are not preempted because although she agrees that such statements are permissible structure/function claims, it is still incumbent upon the manufacturer to ensure that such statements are not false and misleading. Plaintiff states that under Defendants' logic, they could sell anything, falsely claim that it helps memory function, and any falsity claim would be preempted. The Court is not persuaded by Plaintiff's mischaracterization of the federal requirements. As stated above, the first requirement for structure/function claims under the NLEA is that the manufacturer has substantiation that the statement is truthful and not misleading. While not defined, a common-sense interpretation of substantiation involves competent and reliable scientific evidence. The federal labeling requirements prevent a manufacturer from circumventing the substantiation requirements and making improbable representations where no competent and reliable scientific evidence would exist. As was discussed in this Court's previous order on summary judgment both parties offered scientific evidence supporting and contradicting Defendants' Label Claims. [Doc. No. 220.] Although the Ninth Circuit reversed this Court's finding of summary judgment, it affirmed the denial of motions to exclude expert reliance on such evidence.

The Ninth Circuit has also held that an existence of conflicting scientific evidence creates a genuine dispute of material fact for the fact-finder. *See Sonner v. Schwabe N. Am., Inc.*, 911 F.3d 989, 992 (9th Cir. 2018). However, this does not foreclose a finding that Plaintiff's claims are preempted under the NLEA and the Court must first address the issue of preemption. In *Dachauer*, the Ninth Circuit held that the NLEA preempted plaintiff's state law claims that structure/function claims for vitamin E supplements are

false and misleading because the supplements do not prevent cardiovascular disease or reduce all-cause mortality. *Dachauer*, 913 F.3d. at 844. The only claim that was not preempted was that the statements were false and misleading because the supplements *increased* the risk of all-cause mortality. *Id*. at 849. This is because the federal regulations state that a food label "shall be deemed to be misleading if it fails to reveal facts" that are "[m]aterial with respect to consequences which may result from use of the article" under normal conditions of use or the conditions of use that the label prescribes. 21 C.F.R. § 1.21(a)(2). In other words, if a supplement's label recommends taking one capsule per day, and that dose actually causes an increased risk of death—a material fact "with respect to consequences which may result from use of the article"—the FDCA would deem it misleading not to reveal that fact on the label. *Id*. Here, Plaintiff makes no such claim that Defendants failed to reveal material facts with respect to consequences which may result from the use of Defendants' products. If so, such a claim would not be preempted because any requirement to reveal such material facts would be identical to the federal labeling requirements. Plaintiff does not claim that Defendants' products are harmful as opposed to useless, which would have survived preemption.

The federal regulatory framework in place distinguishes structure/function claims from disease claims that claim to diagnose, mitigate, treat, cure, or prevent disease. The latter of which would fall under the classification of a drug that rightfully necessitates more rigorous federal requirements for approval. "[S]ection 403(r)(6)(B) of the act already requires dietary supplement manufacturers to have substantiation that their statements are truthful and non-misleading. [A] 'truthful and non-misleading' standard, unlike the final rule, would not provide any criteria for differentiating between structure/function claims and disease claims." 65 Fed. Reg. at 1003.

Plaintiff's claims would seek to impose requirements under California law that either alters or adds to the requirement that the manufacturer has substantiation that the structure/function claims are truthful and not misleading. Such requirements would directly or indirectly impose obligations or contain provisions not identical to the federal

requirements and mimic a lack of substantiation claim. Here, Defendants' products meet all the requirements for permissible structure/function claims under the NLEA. Plaintiff appears to disagree with the federal statutory scheme for dietary supplements, but the Court cannot accept her invitation to upend it. *Dachauer*, 913 F.3d. at 848. Accordingly, Plaintiff's state false advertising claims are preempted.

IV. CONCLUSION

For the reasons set forth above, Defendants' motion for summary judgment is **GRANTED**. Defendants' motion to decertify the class and both parties' *Daubert* motions are **DENIED as moot**.

It is **SO ORDERED**.

Dated: June 25, 2019

Hon. Cathy Ann Bencivengo
United States District Judge